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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,964	04/15/2004	G. Ian Rowlandson	140822IT (5024-00138)	7468

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EXAMINER	
MORALES, JON ERIC C	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,964	ROWLANDSON ET AL.	
	Examiner	Art Unit	
	Jon-Eric C. Morales	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/15/2004, 5/24/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed on May 24, 2004 has four foreign patent documents (DE 2604460, DE 3303104, DE 4024360, FR 2539978) that fails to comply with 37 CFR 1.98(a)(3) because there is no translation in accordance with MPEP 609.05, or relevance statement. These documents have been placed in the application file, but the information in these four foreign documents has not been considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claim 20 is rejected under 35 U.S.C. 102(a, e) as being anticipated by Sun et al. (U.S. Patent No. 6668188). Sun shows a method of recording, from a rate adaptive

cardiac device, the activity level based on therapy history (implantable device data) (column 4 line 9). Sun additionally discloses gathering intrinsically sensed events from a selected group, which includes real-time EGM, activity level and fitness, and drug dosage, and discomfort complains (non-implant patient data), from system sensors. Shown in figures 4-6 are histograms of correlated data of the therapy history given by the implant and the relation to the real-time EGM, activity level and fitness etc (column 5 lines 29-35).

4. Claims 1-3 and 6-12 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Peel, III et al. (US Patent No. 6647287).

Regarding claims 1, 2, 6, 9, and 11, Peel, III discloses a cardiovascular monitor that comprises of a method that analyzes aortic blood pressure. It does this by measuring and acquiring continuous radial or ulnar blood pressure with a tonometer or a blood pressure sensor in an artery (implant device data). The method also entails measuring and acquiring a plethysmographic blood pressure, from the patient via their finger, using one or more pulse oximeters (non-implant patient data). By use of a mathematical model for correlation and synchronization, a patient-specific aortic blood pressure waveform is the result from the patients' state and current non-implant cardiac data and measurements acquired (column 34 lines 23-37). The patient specific aortic blood pressure waveform is disclosed for diagnosis of cardiovascular condition and treatment of the patient (Column 1 lines 6-10).

With respect to claims 7, 8, and 10, Peel, III also discloses multiple storage devices that save blood pressure data of a patient and the data of the mathematical

model for later usage (column 29 lines 33-36). As well as a display monitor to show representations of any of the patient data. The data provided can include any of the implantable blood pressure sensors or ECG data (column 29 lines 36-39). The disclosed display monitor is to visually assist in the diagnosis of the condition and effects of the treatments for a patient. Peel, III discloses a selection of choices, including ECG data, plethysmograph, and any one of the pulse oximeter measurements for use in the mathematical models (column 34 lines 33-37).

Regarding claims 3 and 12, Peel, III further shows a time reference is measured for a start of each blood pressure pulse in the ECG measurement (column 34 lines 17-19). This is to synchronize any of the data of the cardiac patient.

5. Claims 15, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Valikai et al. (US Patent No. 5948005). Valikai shows a system that includes an implantable pacemaker, which records heart rate/event data. There is also an external programmer that generates a request signal (polling signal) for the implantable device to communicate with and also has a receiving unit is that acquires heart rate/event data from the implantable device. The external programmer, which includes a histogram program, that uses the data acquired from the patient (sensed PV/PR, PVE's), and the data from an implant (paced AV/AR), correlates them and creates a two-dimensional graphical chart as a signature pattern (column 17 lines 10-25, Fig. 7-8). All the data, heart rate, event, or the histogram graph can be displayed on the external programmer display (column 22 lines 50-67, column 23 10-11, column 24 lines 1-9).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peel, III et al. (US Patent No. 6647287) as applied to claims 1 and 10, in view of Shimoni (US Patent No. 4616333). Peel, III substantially discloses the invention as claimed, see rejection to claims 1 and 10 above, however does not teach alignment of non-implant and implant cardiac data to at least one fiducial point. Shimoni discloses a method that obtains a first set of values dealing with data (any form of data) with a certain number of points, then obtaining a second set of data (any type of data) with the same number of points as the first set, the selecting a subset of data points. Then selecting a fiducial value within the first data set and another fiducial point in the subset. Theses values are used as points for alignment with use of a calculation with the first set and the subset data points (column 2 lines 63-68 column 3 lines 6-13). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Peel, III by adding the calculation process of two data sets with use of a fiducial point as a marker as taught by Shimoni in order to facilitate an alignment and correlation of two data sets.

8. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai et al. (US Patent No. 5948005) as applied to claim 15, and further in view of Bardy (US 2002/0099302). Valikai substantially discloses the invention as claimed, see rejection to claim 15 above, however Valikai does not teach the monitoring system of the patient is adapted to communicate with other devices on a network and the data can be received for the monitor from the networks other devices. Bardy discloses a system that sends data from the implantable medical device to an external medical device. The external device then sends the data to a server via an inter-network. This data is placed into a patient care file on a database. The patient care file, on the database, can be accessed by medical devices located on the network for later use (page 3 section 0032). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the system and implantable medical device (i.e. pacemaker) of Valikai by adding the inter-network server communication to a database, as taught by Bardy in order to exchange patient data and store data on a centralized database for later use.

9. Claims 4 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Peel, III et al. (US Patent No. 6647287) as applied to claims 1 and 10, and further in view of Stomberg et al. (US 2005/0103351). Peel, III substantially discloses the invention as claimed, see rejection to claims 1 and 6 above, however does not teach a synchronization with time of data from an non-implantable medical device and data from an implantable medical device. Stomberg discloses a method using an external medical device as a reference time when taking measurements of time with the implantable

medical device. This is to allow for correction of a time drift that occurs in an implantable medical device (page 6 sections [0061-0063]). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Peel, III by adding the time synchronization method, that uses a at least one time reference of a external medical device and a time reference of the clock in an implantable medical device, as taught by Stomberg in order to facilitate a correction of any type of time drift that can occur from a implantable medical device.

Response to Arguments

10. Applicant's arguments filed 10/23/2006 have been fully considered but they are not persuasive.

In response to applicants arguments regarding claim 20, examiner finds that the Sun et al. (US Patent No. 668188) does teach acquiring separate patient data, as well as implant data from an implantable cardiac device (column 4 line 9). Sun discloses device rate adaptive therapy that the implantable medical device delivers (ATR, ATP, CV shock, etc figure 4-6). The therapy history (implant data) is correlated along with intrinsically sensed data (separate patient data) from the system sensors (column 5 lines 29-35).

Regarding arguments to claims 1-3 and 6-12 examiner finds that the Peel, III et al. (US Patent No. 6647287) does actually teach the step of synchronizing non-implant cardiac data with the implant cardiac data. Peel, III et al. discloses that finger waveforms (non-implant cardiac data) are shifted to be synchronous to the aortic waveforms (implant cardiac data) (Column 16 lines 60-63, column 19 lines 36-39). Peel

as well discloses that a radial-aortic model transfer function is converted to a time domain to produce a radial-to-aortic model for reconstructing the aortic waveform (signature pattern) (column 21 lines 46-52).

In response to applicants arguments regarding claims 15,16, and 19 examiner finds that the Valikai et al. (US Patent No. 5948005) does teach a data acquisition of non-implant cardiac data from the patient and correlate the implant cardiac data and the non-implant cardiac data. Valikai shows that a histogram is created from a correlation of paced event (implant data) values and values of a sensed event and a premature ventricular event (non-implant data).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patent and patent application publications are cited and further show the state of the art with respect to implant cardiac data and non-implant cardiac data correlation and synchronization in general:

Manolas - US 2003/0204145

Crosby et al. - US 7074194

Hirsh US - 7054679

Sahai - US 6654631

Raymond et al. - US 6640134

Ripart - US 6385485

Sohma et al. - US 6129677

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is (571) 272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JEM
11/15/2006